

Draft Guidance for Industry and FDA Staff

Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended -- Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

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**When final, this document will supersede the draft guidance entitled:
Compliance with Section 301 of the Medical Device User Fee and
Modernization Act of 2002 – Identification of Manufacturer of Medical
Devices**

Comments and suggestions regarding this draft document should be submitted within 30 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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For questions regarding this document contact Casper E. Uldriks at the Center for Devices and Radiological Health (CDRH) at 240-276-0106 or at casper.uldriks@fda.hhs.gov.



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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Preface

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Draft Guidance for Industry and FDA Staff

Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

On October 26, 2002, section 301 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250) amended section 502 of the Federal Food, Drug, and Cosmetic Act (the Act) to require a device, or an attachment to the device, to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer. An important revision was made to section 502(u) of the Act by the Medical Device User Fee Stabilization Act of 2005 (MDUFSA) (Public Law 109-43), which became law on August 1, 2005.

MDUFSA amended section 502(u) by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Section 502(u) no longer sets forth requirements for original equipment manufacturers (OEMs), unless those manufacturers also reprocess single-use devices. Under the amended provision, if the original device or an attachment to it does not prominently and conspicuously bear the name of the manufacturer of the original device, a generally recognized abbreviation of such name,

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or a unique and generally recognized symbol identifying the manufacturer, the manufacturer who reprocesses the SUD may identify itself using a detachable label on the device's packaging. The detachable label is intended to be affixed to the medical record of a patient by the user of the reprocessed SUD.

MDUFSA also requires that FDA issue guidance identifying the circumstances in which the name, abbreviation, or symbol of the manufacturer of an original device is not "prominent and conspicuous" under section 502(u) of the Act. This guidance document, when finalized, will implement this MDUFSA requirement. Because section 502(u) requires that a reprocessed SUD or its attachment prominently and conspicuously bear the name of the reprocessor, except as described above, this document also provides guidance for reproducers in determining whether their names, abbreviations, or symbols placed on reprocessed SUDs are prominent and conspicuous.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance documents means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This draft guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at <http://www.fda.gov/cdrh/ombudsman/>.

II. Definitions

For the purposes of this guidance, FDA has defined the following terms:

Attachment: An article secured to a device in such a way that it cannot be removed inadvertently.

Detachable label: A removable label on the device packaging that identifies the manufacturer who reprocessed the SUD and is intended to be affixed to the patient record.

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Mark: A name, generally recognized abbreviation of such name, or a unique and generally recognized symbol that identifies a particular manufacturer.

Prominent and conspicuous: A manner of marking a device, as required by section 502(u) of the Act, such that the manufacturer's mark is apparent to the user under ordinary conditions of use.

Reprocessor: A manufacturer who subjects a previously used SUD to additional processing and manufacturing for the purpose of an additional single use on a patient.

Single-Use Device: A device that is intended for one use, or on a single patient during a single procedure.

III. WHO DOES THIS GUIDANCE COVER?

This guidance applies to all manufacturers who reprocess single-use devices; therefore, it also applies to OEMs who reprocess SUDs.

IV. HOW DO I KNOW WHETHER THE MARK OF A MANUFACTURER IS PROMINENT AND CONSPICUOUS?

A. We recommend considering the following factors when deciding whether a manufacturer's mark is prominent and conspicuous:

1. Available space on the device itself
2. Contrast
3. Meaning
4. Font or Graphic Readability

B. You may use the following information and examples to help you decide whether a manufacturer's mark is prominent and conspicuous based on the above:

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1. **Available space:** Is there enough space for the manufacturer's mark so that it can be recognized under ordinary conditions of use, such as in an operating room, emergency room, or ambulance?

For example:

The area of space the size of the side of a common ink pen would likely be adequate to display the mark of the manufacturer.

The area of space the size of the head of a common thumbtack would likely not be adequate to display the mark of the manufacturer.

2. **Contrast:** We recommend that the difference between the color of the manufacturer's mark and the color of the background should make the manufacturer's name or mark apparent to the user under ordinary conditions of use.

For example:

A manufacturer's name using a dark color against a light background creates a contrast that should make the identification apparent.

A manufacturer's name using a light color against a background that is different but not very much darker in color will make it less likely that the identification will be apparent under ordinary conditions of use.

3. **Font or Graphic Readability:** Is the style of the text easy to read and large enough to see during ordinary conditions of use? The actual print and size of the name should be sufficiently clear to enable it to be read under ordinary conditions of use.

For example:

Newspapers, magazines, business letters, or mass media advertisements use a size and style of type that users can read easily.

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Office pens usually bear the mark of the manufacturer or vendor. The name on the pen is large enough so the user can read it while using the pen.

A script that is so ornate or elaborate that the name cannot be easily read will likely make the essential information less readable.

4. Meaning: Will the user understand the manufacturer's mark that appears on the product?

Assuming that the manufacturer has considered available space, contrast, and readability, FDA believes the full name of the manufacturer will be understandable during ordinary conditions of use. When a manufacturer uses an abbreviation of the name, or a symbol, instead of the full name, the manufacturer should use an abbreviation that is closely related to the full name or a unique and recognizable symbol that is associated with the manufacturer.

For example:

When a product bears a manufacturer's name, such as "American Business Company, Inc.," or "XYZ, Inc.," the user should be able to identify the manufacturer.

When a product manufactured by the Long Reprocessing Corporation is identified with the word "Long," the agency believes that the manufacturer will be identifiable under ordinary conditions of use.

When a product bears a unique mark that is generally recognized and associated with the manufacturer, such as an emblem or hood ornament on a car, the user should be able to identify the manufacturer under ordinary conditions of use.

A mark that is generic or not easily identified with a particular manufacturer, such as a hollow circle, will probably not help a user identify the manufacturer.

Note: We also recommend that you consider this factor in determining whether an abbreviation or symbol is "generally recognized" under section 502(u) of the Act.

V. WHEN IS THIS NEW LABELING REQUIREMENT EFFECTIVE?

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The requirement that a reprocessed SUD, or an attachment to the SUD, must bear the reprocessor's mark is effective on one of the following dates, whichever is later:

1. August 1, 2006, which is 12 months after the law was enacted on August 1, 2005

E.g., if the original device or an attachment to it bears the OEM's mark prominently and conspicuously on July 1, 2006, then the reprocessed SUD or its attachment must prominently and conspicuously bear the mark of the reprocessor no later than August 1, 2006.

OR

2. The date, after August 1, 2006, on which the original device or an attachment to it first bears the OEM's mark prominently and conspicuously. If the original device or an attachment to it did not prominently and conspicuously bear the OEM's mark prior to August 1, 2006, but does so at any later date, then the reprocessed SUD or its attachment must prominently and conspicuously bear the mark of the reprocessor before the reprocessed device may be legally marketed.

For example, if the original device first prominently and conspicuously bears the OEM's mark on September 1, 2006, at that point in time a reprocessor must prominently and conspicuously use its own mark on the reprocessed device or its attachment before marketing.

After August 1, 2006, even if the original device or an attachment to it does not bear the OEM's mark (the OEM's mark absent or is not prominent and conspicuous), the reprocessed SUD must identify the reprocessor. Under this circumstance, the reprocessor may identify itself through use of a detachable label on the packaging of the SUD, as described below.

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VI. WHEN SHOULD A REPROCESSOR PLACE ITS MARK ON A DEVICE, USE A DETACHABLE LABEL, OR USE AN ATTACHMENT?

According to section 502(u) of the Act, a reprocessed SUD, or an attachment to it, must prominently and conspicuously bear the name of the manufacturer of the reprocessed device, a generally recognized abbreviation of the name, or a unique and generally recognized symbol identifying such manufacturer. The only exception to this requirement is when the original device, or an attachment to it, does not prominently and conspicuously identify the name of the original equipment manufacturer, a generally recognized abbreviation of the name, or a unique and generally recognized symbol identifying such manufacturer. Under this circumstance, the reprocessor may use a detachable label on the packaging to identify the manufacturer of the reprocessed device.

As stated in MDUFSA, the detachable label is intended to be affixed to the medical record of a patient. FDA therefore recommends that this label contain a statement directing a practitioner to remove the detachable label and affix it to the patient's medical record when the reprocessed SUD is used.

If the original equipment manufacturer has marked the device in such a way that there is little or no usable space for a reprocessor to prominently and conspicuously mark the device, the reprocessor may satisfy the labeling requirement of section 502(u) through the use of an attachment to the device.

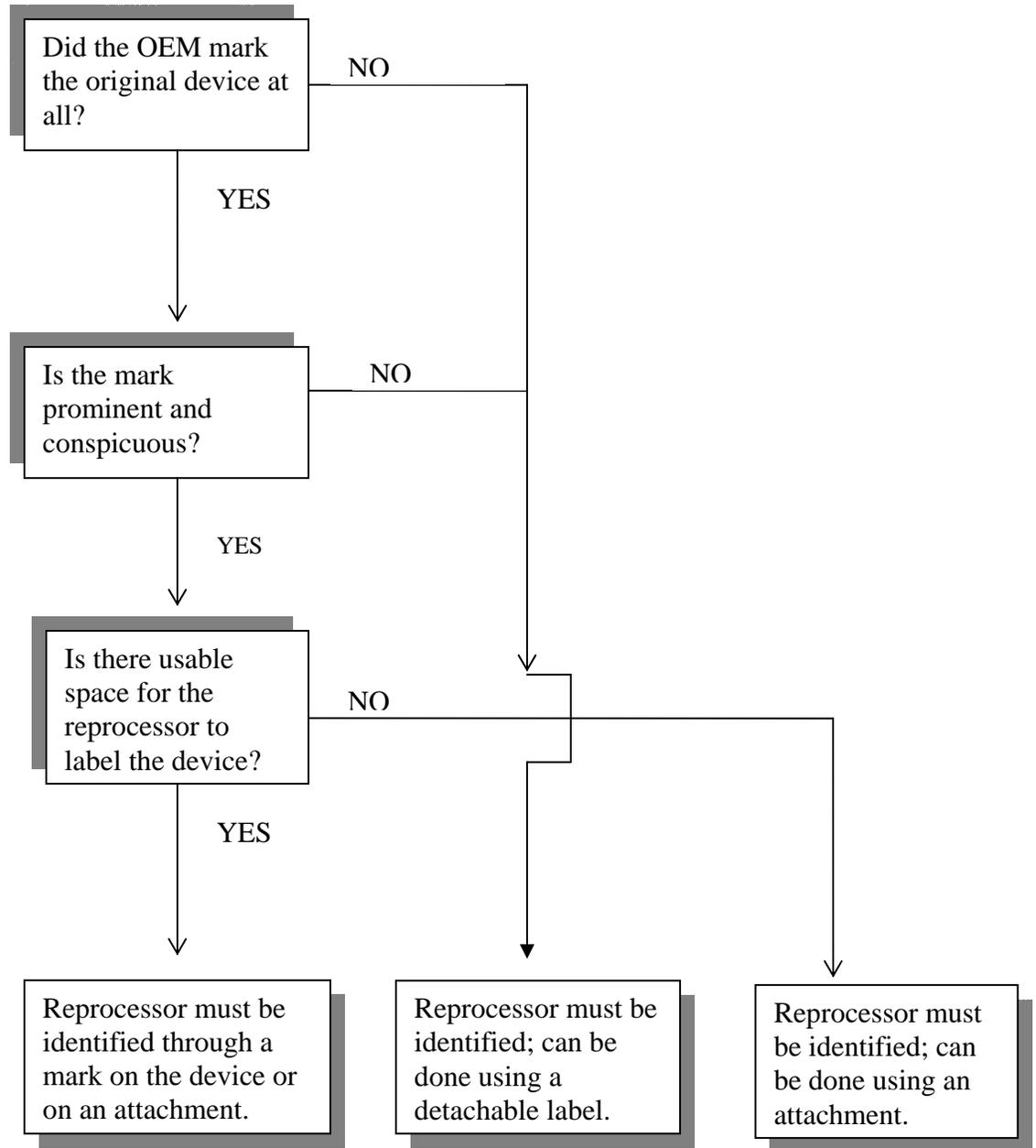
The following flow chart should help you decide whether you should place your mark on the device, use a detachable label, or use an attachment.

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REPROCESSOR'S DECISION FLOW CHART

**DO I PLACE MY MARK ON THE DEVICE, USE A DETACHABLE LABEL, OR
USE AN ATTACHMENT?***



***Section 502(u) of the Federal Food, Drug, and Cosmetic Act, as amended.**

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VII. CAN A REPROCESSOR OBTAIN A WAIVER FROM THIS LABELING PROVISION?

No. Section 502(u) does not provide for a waiver from the labeling requirement.